REMARKS

This paper responds to the Office Action of August 21, 2008 in which the Examiner rejected claims 1, 4-7, 9-16 and 18 under 35 U.S.C. § 102(b) and rejected claims 2, 3 and 8 under 35 U.S.C. § 103(a).

By this paper, claims 1, 11 and 18 have been amended and claim 12 has been canceled. In accordance with the Examiner's suggestion at page 3 of the Office Action and in the Examiner Interview Summary of October 27, 2008, claims 1 and 18 have been amended to more clearly define the structure of the housing and its relation to the inductive charging element, and to more clearly define the relation of the capacitor to the inductive charging element. Claim 8 has been amended to more clearly define the relationship of the DC/DC converter to the drive system and capacitor. No new matter has been added.

Reconsideration and allowance are requested.

Summary of Interview

The October 23, 2008 interview between the Examiner and Bridget Hayden is appreciated. Claim 1 and one of the cited references, US Patent 6,056,716 ("D'Antonio"), were discussed and, while agreement with respect to the claims was not reached, it appears that progress was made toward putting the application into condition for allowance. In particular, the Examiner's suggestion regarding further structural definition is reflected in the above amendments.

Rejection under 35 U.S.C. §§ 102(b) and 103(a)

The claimed invention is directed to an injection device with a drive system, "at least one capacitor providing the sole electric power for powering the drive system for performing at least one injection," and an external charging device, wherein "the drive system remains operable for expelling a dosage after the external charging device has been removed from the at least one inductive charging element by discharging the charge from the at least one capacitor."

An initial observation regarding the claimed invention is that using a capacitor as the sole electric power for powering the drive system of an injection device so that the drive system remains operable after removal of the charging device contrasts with the typical installation and

use a capacitor, which typically operates together with and is non-detachably coupled to a power source. The references cited by the Examiner and discussed below disclose capacitors that operate with a connected power source according to a capacitor's typical installation and use, and there is no indication that the references may be modified to reach the claimed invention.

Claims 1, 2, 4-7, 9-16 and 18 are not anticipated or rendered obvious over D'Antonio

Claims 1, 4-7, 9-16 and 18 were rejected under 35 U.S.C. § 102(b) over D'Antonio, and claim 2 was rejected under 35 U.S.C. § 103(a) over D'Antonio. The §§ 102 and 103 rejections over D'Antonio are traversed for at least the following reasons.

Independent claim 1, as amended, is directed to an injection device with "at least one inductive charging element" coupled to a capacitor within the injection device and "at least partially arranged at an exterior face of the housing for removable coupling to an external charging device" whereby the injection device remains operable for expelling a dosage after the charging device has been removed by discharging the charge from the at least one capacitor. Independent claims 18, as amended, is directed to an injection device with a capacitor and "at least one inductive charging element" "configured to receive an external charging device charge" and deliver the charge to the capacitor wherein the "charging device is external to the injection device housing and is removable from the injection device housing prior to the injection device injecting the medicament." According to each of the independent claims, the injection device is operable when separated from the external charging device due to one or more capacitors housed therein storing the energy required for driving the injection device drive system. The energy stored in the capacitor is received from the inductive charging element, which is suitably arranged relative to an exterior face of the injection device housing.

D'Antonio discloses a hypodermic fluid dispenser as shown at FIG. 7C, which includes a power pack 950 inserted in access port 954 so that the power pack 950 is connected to electrical contact 952 arranged within the handle of the dispenser. *See D'Antonio*, col. 25, lines 14-45.

The dispenser in combination with capacitor 348 does not anticipate the "injection device" as recited in the independent claims because the D'Antonio capacitor 348 and power

pack 950 are coupled throughout the charging, injecting and recharging processes. D'Antonio states:

> When the charge and corresponding voltage on capacitor 348 reaches a predetermined value the output of the threshold detector 356 will go low and gate 338 is disabled. The predetermined value represents a charge and voltage large enough to advance the motor 221. When the output of detector 356 goes low, the output of inverter 358 goes high to enable transistor 360 to provide a path for discharging the capacitor 348 through the winding of motor 221. As the charge is depleted and the voltage on the capacitor falls below the threshold value of detector 356, the output of detector 356 goes high to enable gate 340 to initiate another cycle of charging capacitor 348; and the output of inverter 358 goes low to disable transistor 360. High speed charging cycles will continue until the flip flop 336 is set to the "1" state which indicates that the energy stored in spring 227 has reached the target value. In the drawing, the output labeled Q_5 is the "1" output of the flip flop 336 and the complement output is termed the "0" output herein.

D'Antonio, column 7, lines 27-45 (emphasis added). There is no disclosure or suggestion in D'Antonio that dispenser electronics may deliver an injection when separated from the power source which provides the "high speed charging cycles." *Id.*

D'Antonio indicates the dispenser is provided with either a power pack 950 in the handle or with an external power pack 972. D'Antonio states:

> Finally, power adapter 968 in FIG. 7D can be inserted into the injector housing in place of power pack 950 to allow for operation from other power sources if the portability of small battery operation is not required. For example, adapter 968 can be connected directly to an adequate source of external power or to power pack 972, wherein the injector is then powered with a non-disposable source of external energy that is transported to the remote location along with the injector, the medications and the health worker units. External source 972 can be a high capacity rechargeable battery or a storage capacitor whose value is large enough to supply N shots before recharge is needed. Recharge of power pack 972 can come from grid power at socket 976 (if available), or as an alternative, a solar panel trickle charger 978, a portable generator 980 or directly from a vehicle's power system 982 if such vehicle is available to the health care workers. In some

> remote locations, powerful solar systems 983 located nearby or on the roof of the health care facility are also conveniently used.

D'Antonio, column 25, lines 27-45. In instances where power pack 950 is replaced with an alternate energy source like power pack 972, there is no disclosure or suggestion that the dispenser may deliver an injection when separated from the power pack 972.

For at least the preceding reasons, reconsideration and withdrawal of the §§ 102 and 103 rejections of claims 1 and 18 are requested. Claims 2, 4-7 and 9-16 depend from claim 1 and are allowable for at least the same reasons.

Claim 3 is not obvious over D'Antonio in view of Avrahami et al.

Claim 3 was rejected under 35 U.S.C. §103(a) over D'Antonio in view of US Patent 6,708,060 ("Avrahami"). This rejection is traversed for at least the following reasons.

Claim 3 depends directly from claim 1. As discussed above, D'Antonio does not disclose or suggest the invention of claim 1, at least because it does not disclose or suggest an injection device operable when separated from an external charging device due to one or more capacitors housed within the injection device that store the energy required for driving the injection device drive system.

The combination of D'Antonio and Avrahami is improper. The Examiner acknowledges D'Antonio does not expressly disclose that the capacitor is a duplex capacitor as claimed in claim 3 and goes on to state:

> Avrahami et al teaches that it is known to have a duplex capacitor for the purpose of modulating charge delivery. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the capacitor as taught by D'Antonio et al with the duplex capacitor as taught by Avrahami et al for the purpose of modulating charge delivery.

Office Action, page 4 (internal citations omitted). However, there is no indication in D'Antonio that there is a deficiency in the capacitor provided by D'Antonio or that one should look beyond the disclosure in D'Antonio to seek an alternate capacitor such as a duplex capacitor. Indeed,

there would be no benefit to changing the D'Antonio reference as suggested to include a duplex capacitor, as claimed in claim 3. Accordingly, the combination of D'Antonio and Avrahami is improper.

Even if the combination of D'Antonio and Avrahami were proper, which it is not, Avrahami is directed to a skin treatment device and does not remedy the disclosure deficiencies of D'Antonio noted above. Thus, the asserted combination would not yield the invention as claimed. Even assuming it would have been obvious to one having ordinary skill at the time of the invention to modify the capacitor of D'Antonio with a duplex capacitor, the modification would not make obvious the invention of claim 3. In Avrahami, "a current source 114 preferably comprises a source of electrical power (for example, a battery) connected in series with an inductive element, which due to pulse charging, exhibits properties of a current source, thereby limiting the power dissipated in underlying epidermal tissue." *Avrahami*, col. 18, ll., 20-24. "[E]nergy storage components such as capacitors and/or inductors can be used to modulate charge delivery." *Avrahami*, column 20, lines 52-54. The capacitors in Avrahami may be considered inductive elements, which are coupled with a source of electrical power to limit power dissipation: "power source 212 . . . and switch 214 are connected in series with a capacitor 216 . . . Capacitor 216 is preferably used in order to limit the total charge delivered through electrodes 120." *Avrahami*, column 21, lines 28-34. However, there is no disclosure or teacing that a capacitor serves as source of electrical power as provided in the present invention. That is, Avrahami, like D'Antonio, does not disclose or suggest using a capacitor in an injection device as a sole source of power such that the injection device is operable when separated from an external charging device. Nor does Avrahami disclose the recited structural relationships between the charging device and the injection device. Accordingly, claim 3 is patentable for at least for the reasons presented above and, further, in view of its additional recitations. Reconsideration and allowance are respectfully requested.

Claim 8 is not obvious over D'Antonio in view of Portner

Claim 8 was rejected under 35 U.S.C. § 103(a) over D'Antonio in view of US Patent 4,360,019 ("Portner"). This rejection is traversed for at least the following reasons.

Claim 8 depends directly from claim 1. As discussed above, D'Antonio does not disclose or suggest the invention of claim 1, at least because it does not disclose or suggest an injection device operable when separated from an external charging device due to one or more capacitors housed within the injection device.

A problem with the asserted D'Antonio/Portner combination is that it is not proper. There would be no reason for one skilled in art to modify D'Antonio to include a DC/DC converter "for the purpose of charging the capacitor to a voltage matching the required voltage from the drive member" (*Office Action*, page 5), particularly because D'Antonio already discloses a device for the very purpose of charging a capacitor to a voltage matching the required voltage from the drive member. D'Antonio discloses three methods for storing energy in preparation to operate a motor: 1) an energy enhancement technique involving charging capacitor 346 using voltage amplification with coil 342 and diode 344, for power sources that do not have the voltage or current capability for directly driving a motor, 2) an energy enhancement technique involving charging capacitor 346 using voltage amplification without coil 342 and diode 344, for power sources that do have the voltage or current capability for directly driving a motor, and 3) "an embodiment whose power source has enough instantaneous energy to drive the motor directly, i.e., one with enough current and voltage capability for driving the motor with no energy enhancement at all." *D'Antonio*, column 17, line 45 to column 18, line 4. The DC/DC charging method in Portner is for "long-life primary batter[ies that] would not provide the high peak currents necessary to energy the solenoid 38, [and] the pulse energy is stored in a capacitor 77. As shown, a flyback type DC-to-DC converter charge s this capacitor to a voltage matching the solenoid requirement." *Portner*, column 9, lines 11-16. Thus, the DC-to-DC converter provided in Portner is the same as the coil 342 and diode 344 in the first method for storing energy in D'Antonio as discussed above because both involve charging a capacitor from power sources that to not have the capability for directly driving a device "for the purpose of charging the capacitor to a voltage matching the required voltage from the drive member." *Office Action*, page 5. Accordingly, one having ordinary skill in the art at the time of the invention would not look to another reference to find a device, such as a DC-to-DC converter, for charging a capacitor due to a power source not have the capability for directly driving a device because such a device is already disclosed in D'Antonio.

Even if the asserted combination is deemed proper, i.e. that there would be some rational and/or benefit to make the combination, Portner discloses an implantable infusion device including a DC/DC converter that does not remedy the above-noted disclosure deficiencies of D'Antonio. The asserted combination would still not disclose or teach every element of the claimed invention, e.g. that an injection device can be operable when separated from an external charging device, or the recited structural relationships. The asserted combination, therefore, would not make obvious the invention of claim 8.

Moreover, claim 8 has been amended to recite the "DC/DC converter [is] operably coupled to the at least one capacitor, said DC/DC converter configured to receive a DC voltage from the capacitor and deliver a constant DC voltage to the drive system." This is in contrast to Portner, which discloses a DC-to-DC converter responsible for charging the capacitor (*Portner*, column 9, lnes 14-16), but which does not deliver a constant DC voltage.

Reconsideration and withdrawal of the rejection are respectfully requested.

Conclusion

This response is being submitted on or before January 21, 2009, with the required fee for a two-month extension of time, making this a timely response. It is believed that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

The application now stands in allowable form, and reconsideration and allowance are respectfully requested. If, however, the Examiner believes there are any issues remaining that could be resolved by a discussion, he is invited to contact the undersigned or Bridget Hayden at (612) 492-6867 to discuss actions that can be taken to reach formal allowance.

Respectfully submitted,

DORSEY & WHITNEY LLP
Customer Number 25763

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By: _____
David E. Bruhn, Reg. No. 36,762
(612) 340-6317